HOUSE OF REPRESENTATIVES TWENTY-EIGHTH LEGISLATURE, 2015 STATE OF HAWAII H.B. NO. ²⁵⁴ H.D. 2 S.D. 1 C.D. 1

A BILL FOR AN ACT

RELATING TO MEDICINES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that biologics are a
 class of medicines available to treat disease. Unlike
 traditional drugs, which are chemically manufactured, biologics
 are manufactured in living cells. Common biologics in use today
 include human growth hormone, injectable treatments for
 arthritis and psoriasis, the Hepatitis B vaccine, and stem cell
 therapy.

8 The term "biosimilars" refers to substitute versions of 9 brand-name biologics, similar to generic versions of brand-name 10 drugs. These substitutes are not exactly identical to brand-11 name biologics but are designed to provide commensurate benefits 12 to patients at lower costs. At least nineteen biosimilars are 13 currently approved for use in the European Union.

14 The Patient Protection and Affordable Care Act, signed into
15 law by President Barack Obama in 2010, created an abbreviated
16 licensure pathway for biological products that are demonstrated
17 to be biosimilar to or interchangeable with a biologic product
18 licensed by the United States Food and Drug Administration
HB254 CD1 HMS 2016-3493
1

H.B. NO. ²⁵⁴ H.D. 2 S.D. 1 C.D. 1

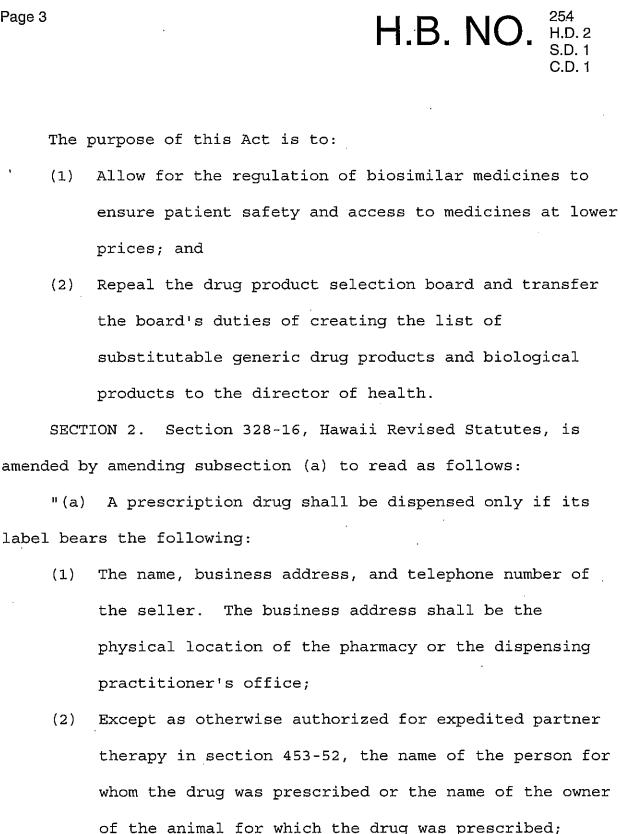
(FDA). In early 2015, the FDA approved its first biosimilar
 drug, Zarxio for use in the United States. Zarxio is used to
 help prevent infections in cancer patients receiving
 chemotherapy and is a close copy of an existing medication
 called Neupogen. Market research reports that there are at
 least one hundred fifty biosimilars in development.

As of September 15, 2015, sixteen states and Puerto Rico have passed legislation to regulate the substitution of biosimilars for brand-name biologics by pharmacists, and at least thirty-one states have considered similar legislation. Other important issues relating to state regulation of biosimilars include the powers and duties of prescribing authorities, notice to patients, safety, and recordkeeping.

14 The legislature further finds that the drug product 15 selection board is no longer necessary and its purpose, namely 16 creating the Hawaii additions and deletions list, is better 17 served by reassigning that responsibility to the director of 18 health and combining the responsibility to amend the list of 19 substitutable generic drug products and biological products with 20 the responsibility the director already has for initially 21 creating that same list.

HB254 CD1 HMS 2016-3493

Page 3



The serial number of the prescription; (3)

HB254 CD1 HMS 2016-3493

1 (4)The date the prescription was prepared; 2 The name of the practitioner if the seller is not the (5)3 practitioner; 4 (6) The name, strength, and quantity of the drug; 5 (7) The "use by" date for the drug, which shall be: 6 (A) The expiration date on the manufacturer's 7 container; or One year from the date the drug is dispensed, 8 (B) whichever is earlier; 9 The number of refills available, if any; 10 (8) In the case of the dispensing of an equivalent generic 11 (9) 12 drug product, the statement "same as (brand name of 13 the drug product prescribed or the referenced listed drug name)", or words of similar meaning; [and] 14 In the case of the dispensing of an interchangeable 15 (10) 16 biological product, the statement "interchangeable 17 with (brand name of the biological product prescribed or the referenced biological drug name)", or words of 18 19 similar meaning; and 20 [(10)] (11) Specific directions for the drug's use; provided that if the specific directions for use are too 21

H.B. NO. ²⁵⁴ H.D. 2

HB254 CD1 HMS 2016-3493

H.B. NO. ²⁵⁴ H.D. 2 S.D. 1 C.D. 1

lengthy for inclusion on the label, the notation "take according to written instructions" may be used if separate written instructions for use are actually issued with the drug by the practitioner or the pharmacist, but in no event shall the notation "take as directed", referring to oral instructions, be considered acceptable.

8 If any prescription for a drug does not indicate the number of 9 times it may be refilled, if any, the pharmacist shall not 10 refill that prescription unless subsequently authorized to do so 11 by the practitioner. The act of dispensing a prescription drug 12 other than a professional sample or medical oxygen contrary to 13 this subsection shall be deemed to be an act that results in a 14 drug being misbranded while held for sale."

15 SECTION 3. Section 328-91, Hawaii Revised Statutes, is 16 amended as follows:

17 1. By adding five new definitions to be appropriately18 inserted and to read:

"<u>"Biological product" or "biologic product" has the same</u>
meaning as defined in Title 42 United States Code section 262,
as the same may be amended.



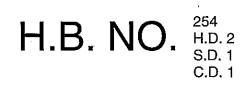
1	"Drug product" means a drug as defined in section 328-1
2	other than a biological product as defined in this part.
3	"Hawaii list of equivalent generic drug products and
4	interchangeable biological products" means the list of
5	equivalent generic drug products and interchangeable biological
6	products, which may include references to the Orange Book, the
7	Purple Book, and other published findings and approvals of the
8	United States Food and Drug Administration, created and
9	published by the director pursuant to the director's authority
10	in this part to approve drug products and biological products
11	that pharmacists may substitute with equivalent generic drug
12	products and interchangeable biological products.
13	"Interchangeable biological product" means a biological
14	product approved by the director as substitutable by pharmacists
15	and included in the Hawaii list of equivalent generic drugs and
16	interchangeable biological products.
17	"Purple Book" means the United States Food and Drug
18	Administration's "List of Licensed Biological Products with
19	Reference Product Exclusivity and Biosimilarity or
20	Interchangeability Evaluations" publication and its cumulative



H.B. NO. ²⁵⁴ H.D. 2 S.D. 1 C.D. 1

1	supplements, which include a list of licensed biological
2	products with biosimilarity and interchangeability evaluations."
3	2. By amending the definition of "equivalent generic drug
4	product" to read:
5	""Equivalent generic drug product" means a drug product
6	[with_the_same_established_name, active_ingredient_strength,
7	quantity, and dosage form as the drug product identified in the
8	prescription, and: (1) that is listed as therapeutically
9	equivalent (i.e., addition) in the current Hawaii additions and
10	deletions list; or (2) that is listed in the compendia of
11	therapeutically equivalent generic drug products and is not
12	listed as therapeutically inequivalent (i.e., deletion) in the
13	Hawaii additions and deletions list.] approved by the director
14	as substitutable by pharmacists and included in the Hawaii list
15	of equivalent generic drug products and interchangeable
16	biological products."
17	3. By amending the definition of "savings" to read:
18	""Savings" means the financial benefit derived from
19	utilizing the substituted equivalent generic drug product or
20	interchangeable biological product from the perspective of the
21	consumer or the ultimate payer, including third party payers."

HB254 CD1 HMS 2016-3493



1	4. By repealing the definition of "board".
2	[""Board" means the drug product selection board."]
3	5. By repealing the definition of "compendia of
4	therapeutically equivalent generic drug products".
5	[""Compendia of therapeutically equivalent generic drug
6	products" means the Orange Book and any United States Food and
7	Drug-Administration documentation of any United States Food and
8	Drug Administration approved generic drug product with
9	therapeutic equivalency evaluations, including but not limited
10	to:
11	(1) Letters of approval of Abbreviated New Drug
12	Applications with therapeutic equivalency evaluations;
13	(2) Published listings of approved New Drug Applications
14	or approved Abbreviated New Drug Applications with
15	therapeutic equivalency evaluations; and
16	(3) Listings of first-time generics with therapeutic
17	equivalency evaluations, adopted by the director."]
18	6. By repealing the definition of "Hawaii additions and
19	deletions list".
20	[" "Hawaii additions and deletions list" means:

HB254 CD1 HMS 2016-3493

. 8

H.B. NO. ²⁵⁴ H.D. 2 S.D. 1 C.D. 1

1	(1)	A list of drug products that the board has determined
2		to be safe, effective, and therapeutically equivalent
3		generic drug products-but are not in the compendia of
4		therapeutically equivalent generic drugs; and
5	-(2) -	A list of drug products that are included in the
6		compendia of therapeutically equivalent generic drugs,
7		but that the board has determined not to be safe,
8		effective, therapeutically equivalent, or
9		bioequivalent-generic drug products."]
10	7.	By repealing the definition of "multiple source drug".
11	[" "M	ultiple source drug" means a drug marketed or sold by
12	two or m e	ere-manufacturers or labelers or a drug marketed or sold
13	by the s a	me manufacturer or labeler under two or more different
14	brand nam	es, or both, under a brand name and without such a
15	<pre>mame."]</pre>	
16	SECI	ION 4. Section 328-92, Hawaii Revised Statutes, is
17	amended t	o read as follows:
18	"§32	8-92 Drug product and biological product selection.
19	(a) When	filling a prescription order for a drug prescribed by
20	its brand	l name, a pharmacist or the pharmacist's authorized
21	agent sha	all:

•



1 Offer to the consumer an equivalent generic drug (1)2 product or an interchangeable biological product from 3 the [formulary] Hawaii list of equivalent generic drug 4 products and interchangeable biological products 5 adopted pursuant to section 328-96; [and] 6 (2)Upon the request of the consumer, inform the consumer 7 of the savings; and 8 (3) Inform the consumer of the consumer's right to refuse 9 substitution. 10 The pharmacist shall substitute an equivalent generic drug 11 product or an interchangeable biological product if the 12 practitioner does not prohibit substitution under subsection 13 (b), and the substitute equivalent generic drug product or 14 interchangeable biological product results in a savings. The 15 pharmacist shall not substitute if the consumer refuses. 16 (b) The pharmacist shall not substitute an equivalent 17 generic drug product or an interchangeable biological product if the practitioner indicates "brand medically necessary" or words 18 19 of similar meaning on the prescription. The designation "brand 20 medically necessary" or other similar words or phrases must be 21 handwritten by the practitioner and shall not be preprinted or

HB254 CD1 HMS 2016-3493

10

254 H.D. 2

H.B. NO.

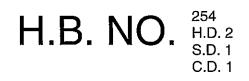
1 stamped on the written prescription. The pharmacist shall not 2 substitute an equivalent generic drug product or an 3 . interchangeable biological product if a prescription is orally 4 or electronically ordered and the practitioner or authorized 5 employee of the practitioner indicates "brand medically 6 necessary" or other similar words or phrases. 7 The pharmacist shall note the practitioner's instructions 8 on the prescription record required to be maintained under 9 section 328-17.7. 10 This subsection shall not apply when it does not comply 11 with any federal requirement for services reimbursable by 12 medicaid or medicare. 13 (c) The pharmacist shall not substitute an equivalent 14 generic drug product or an interchangeable biological product 15 for any prescription for an anti-epileptic drug, except upon the 16 consent of the practitioner and the patient or the patient's

H.B. NO. ²⁵⁴ H.D. 2

17 parent or guardian. This narrow exception for epileptic
18 patients shall not be construed as a policy decision to make
19 exceptions for any other conditions.

20 (d) Within two business days following the dispensing of a
 21 biological product, the dispensing pharmacist or the

HB254 CD1 HMS 2016-3493



.

,

.

1	pharmacist's designee shall communicate to the practitioner the				
2	specific product provided to the patient, including the name of				
3	the product and the manufacturer. The communication shall be				
4	conveyed by making an entry that is electronically accessible to				
5	the practitioner through:				
6	(1) An interoperable electronic medical records system;				
7	(2) An electronic prescribing technology;				
8	(3) A pharmacy benefit management system; or				
9	(4) A pharmacy record.				
10	(e) Entry into an electronic records system as described				
11	in subsection (d) is presumed to provide notice to the				
12	prescriber. Otherwise, the pharmacist shall communicate the				
13	biological product dispensed to the prescriber using facsimile,				
14	telephone, electronic transmission, or other prevailing means,				
15	provided that communication shall not be required where:				
16	(1) There is no interchangeable biological product				
17	approved by the United States Food and Drug				
18	Administration for the product prescribed; or				
19	(2) A refill prescription is not changed from the product				
20	dispensed on the prior filling of the prescription.				

[-(d)-] (f) The county prosecutors and the attorney general
may bring action upon complaint by an aggrieved person or upon
their own motion in the name of the State against any person to
enjoin any violation of this part."

H.B. NO. ²⁵⁴ H.D. 2

5 SECTION 5. Section 328-94, Hawaii Revised Statutes, is
6 amended to read as follows:

7 "§328-94 Prescription record. Each pharmacist or
8 practitioner shall maintain a record of any substitution of an
9 equivalent generic drug product <u>or an interchangeable biological</u>
10 <u>product</u> for a prescribed brand name drug product as provided in
11 this part."

SECTION 6. Section 328-96, Hawaii Revised Statutes, isamended to read as follows:

14 "§328-96 [Drug formulary; Hawaii additions and deletions 15 list.] Hawaii list of equivalent generic drug products and 16 interchangeable biological products. (a) The [board] director 17 may adopt rules, pursuant to chapter 91, to effectuate the 18 purpose of this part. Without regard to chapter 91, the 19 director may adopt as rules, and amend as necessary, the 20 [compendia of therapeutically equivalent generic drug products 21 as the state drug formulary of equivalent multiple source drug

HB254 CD1 HMS 2016-3493

H.B. NO. ²⁵⁴ H.D. 2 S.D. 1 C.D. 1

1	products. The board may-adopt rules pursuant to chapter 91 to
2	establish a Hawaii additions and deletions list. Upon the
3	adoption of the compendia of therapeutically equivalent generic
4	drug products by the director, the department shall notify all
5	pharmacics in the State and other interested individuals, within
6	thirty working days, that the formulary has been updated.]
7	Hawaii list of equivalent generic drug products and
8	interchangeable biological products, which shall serve as the
9	state list of substitutable equivalent generic drug products and
10	interchangeable biological products. The director's approval of
11	the substitutability of equivalent generic drug products and
12	interchangeable biological products shall be informed by the
13	findings of the United States Food and Drug Administration,
14	which are documented and periodically updated through the
15	following:
16	(1) For a generic drug product: the Orange Book and any
17	United States Food and Drug Administration
18	documentation of any United States Food and Drug
19	Administration-approved generic drug product with
20	therapeutic equivalency, including:

.

1		(A)	Letters of approval of Abbreviated New Drug
2			Applications with therapeutic equivalency
3			evaluations;
4		<u>(B)</u>	Published listings of approved New Drug
5			Applications or approved Abbreviated New Drug
6			Applications with therapeutic equivalency
7			evaluations; and
8		(C)	Listing of first time generics with therapeutic
9			equivalency evaluations;
10	(2)	For	a biological product: approval under the Public
11		Heal	th Service Act, the Purple Book, and any United
12		Stat	es Food and Drug Administration documentation of
13		any	United States Food and Drug Administration-
14		appr	oved interchangeability determination, including:
15		<u>(A)</u>	Letters of approval of Biologic Licensing
16			Applications with a determination that the
17			biological product meets the criteria for
18			interchangeability as set forth in title 42
19			United States Code section 262(k)(4); and
20		<u>(B)</u>	Published listings of approved Biologic Licensing
21			Applications with a determination that the



15

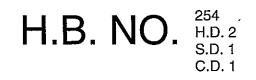
254 H.D. 2 S.D. 1 C.D. 1

H.B. NO.

H.B. NO. ²⁵⁴ H.D. 2 S.D. 1 C.D. 1

1			biological product meets the criteria for
2			interchangeability as set forth in Title 42
3		•	United States Code section 262(k)(4); and
4	(3)	For	a biological product approved under the Federal
5		Food	l, Drug, and Cosmetic Act: the Orange Book and any
6		Unit	ed States Food and Drug Administration
7		docu	mentation of any United States Food and Drug
8		Admi	nistration-approved interchangeability
9		dete	ermination, including:
10		<u>(A)</u>	Letters of approval of approved New Drug
11			Applications or approved Abbreviated New Drug
12			Applications with therapeutic equivalency
13			evaluations; and
14		<u>(B)</u>	Published listings of approved New Drug
15			Applications or approved Abbreviated New Drug
16			Applications with therapeutic equivalency
17			evaluations.
18	(b)	The	director shall maintain an official record of, and
19	update as	nece	essary, the Hawaii list of equivalent generic drugs
20	and inter	chang	geable biological products electronically on the





1	department's website, which shall be accessible to pharmacists
2	and other interested persons.
3	(c) The Hawaii [additions and deletions] list [may list
4	additional] of equivalent generic drug products and
5	interchangeable biological products shall only include
6	substitutable generic drug products and interchangeable
7	biological products that are determined by the [board] director
8	to be safe, effective, and therapeutically equivalent [. The
9	Hawaii additions and deletions list may delete drug products
10	listed in the compendia of therapeutically equivalent generic
11	drug] or interchangeable. The director shall not approve as
12	substitutable, and the Hawaii list of equivalent generic drug
13	products and interchangeable biological products shall not
14	include, any biological products that the United States Food and
15	Drug Administration has neither licensed and determined as
16	meeting the standards for interchangeability pursuant to Title
17	42 United States Code section 262(k)(4) nor determined as
18	therapeutically equivalent as set forth in the latest edition of
19	or supplement to the United States Food and Drug
20	Administration's approved drug products with therapeutic
21	equivalence evaluations.



1	(d) The director may remove from the Hawaii list of
2	equivalent generic drug products and interchangeable biological
3	products any products upon the [board's] director's finding that
4	[product] the safety, quality, efficacy, or therapeutic
5	equivalency or bioequivalency, as appropriate, is not adequately
6	assured.
7	[(b) Pursuant to chapter 91, the Hawaii additions and
8	deletions list may be changed, added to, or deleted from as the
9	board-deems-appropriate.]
10	(e) Any person who requests that any [change] modification
11	be made to, or that a drug product or biological product be
12	[included or] added to [or deleted] <u>or removed</u> from <u>,</u> the Hawaii
13	[additions and deletions] list of equivalent generic drug
14	products and interchangeable biological products shall have the
15	burden of proof to show cause why the [change, inclusion,]
16	modification, addition, or [deletion] removal should be made.
17	[(c) The board shall revise or supplement the Hawaii
18	additions and deletions list as necessary.
19	(d) The department shall provide for distribution of the
20	Hawaii additions and deletions list and its revisions and
21	supplements; and the dissemination of notices of changes to the

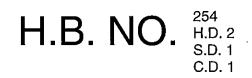
HB254 CD1 HMS 2016-3493

18

254 H.D. 2 S.D. 1 C.D. 1

.

H.B. NO.



1

1	compendia of therapeutically equivalent generic drug products to
2	all pharmacies in the State and to any other interested
3	individuals. The department may establish fees to be charged to
4	persons who receive the Hawaii additions and deletions list and
5	its revisions and supplements, and notices of changes to the
6	compendia of therapeutically equivalent generic drug products.
7	The amounts of the fees charged shall be approximately the same
8	as the costs of producing and distributing the Hawaii additions
9	and deletions list and its revisions and supplements, and the
10	notices of changes-to the compendia of therapeutically
11	equivalent generie drug products.
12	(e)] (f) Each pharmacy in the State shall [+
13	(1) Maintain and] update [the compendia of therapeutically
14	equivalent generic drug products] and maintain its
15	physical copies and electronic records of the Hawaii
16	list of equivalent generic drug products and
17	interchangeable biological products as it is approved
18	and periodically updated and amended by the director $[+$
19	and
20	(2) Obtain the Hawaii additions and deletions list].

HB254 CD1 HMS 2016-3493

H.B. NO. ²⁵⁴ H.D. 2 S.D. 1 C.D. 1

. 1	$\left[\frac{f}{f}\right]$ (g) The department shall provide for public
2	education regarding the provisions of this part and shall
3	monitor the effects of this part."
4	SECTION 7. Section 328-97, Hawaii Revised Statutes, is
5	amended to read as follows:
6	"[+]§328-97[+] Posting requirements. Every pharmacy shall
7	prominently display, in clear and unobstructed public view, a
8	sign in block letters [which] <u>that</u> shall read:
9	"HAWAII LAW REQUIRES THAT LESS EXPENSIVE GENERICALLY EQUIVALENT
10	DRUG PRODUCTS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS BE OFFERED
11	TO THE CONSUMER. CONSULT YOUR PHYSICIAN AND PHARMACIST
12	CONCERNING THE AVAILABILITY OF THE LEAST EXPENSIVE DRUG PRODUCT
13	FOR YOUR USE."
14	The letters must be at least one inch in height."
15	SECTION 8. Section 328-98, Hawaii Revised Statutes, is
16	amended to read as follows:
17	"§328-98 Pharmacist liability. A pharmacist who selects
18	an equivalent <u>generic</u> drug product <u>or an interchangeable</u>
19	biological product pursuant to this part assumes no greater
20	liability for selecting the dispensed drug product than would be

HB254 CD1 HMS 2016-3493

Page 21

incurred in filling a prescription for a drug product prescribed
 by its established name."

3 SECTION 9. Section 328-95, Hawaii Revised Statutes, is
4 repealed.

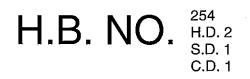
5 ["[\$328-95] Establishment of drug product selection board. (a) There is established a drug product selection-board 6 7 composed of one representative from the department of health, one-representátive from either the University of Hawaii school 8 9 of medicine or the University of Hawaii school of public health; 10 two physicians, and two pharmacists; to be appointed by the 11 governor with the advice and consent of the senate, pursuant to 12 section 26-34. The board shall designate the chairperson from its duly appointed membership. A seventh member shall be the 13 director of health or the director's designated representative. 14 (b) The-drug product selection board shall be placed, for 15 16 administrative purposes only, within the department of health. 17 (c) The members of the drug product selection board shall serve without compensation, but shall be reimbursed for 18 19 expenses, including travel expenses, incurred in the performance 20 of their duties."]

HB254 CD1 HMS 2016-3493

21

254 H.D. 2

H.B. NO.



SECTION 10. Statutory material to be repealed is bracketed
 and stricken. New statutory material is underscored.

3 SECTION 11. This Act shall take effect on July 1, 2016.





Report Title:

Biosimilar Medicines; Interchangeable Biological Products; Hawaii List of Equivalent Generic Drug Products and Interchangeable Biological Products; Director of Health

Description:

Allows for and regulates the dispensing of interchangeable biological products. Requires pharmacists to inform consumers of interchangeable biological products from the Hawaii list when filling a prescription order and to communicate the product name and manufacturer to the practitioner after dispensing the product. Repeals the Drug Product Selection Board. (HB254 CD1)

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.

